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10/501,487	07/13/2004	Mitsuaki Oshima	AOY-3983US	9517
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P O BOX 980			TURK, NEIL N	
VALLEY FORGE, PA 19482-0980			ART UNIT	PAPER NUMBER
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Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

## Office Action Summary

Application No.

10/501,487

Applicant(s)

OSHIMA, MITSUAKI

Examiner

Neil Turk

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

### Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE \_\_\_\_ MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

### Status

- 1) ☒ Responsive to communication(s) filed on 11/09/07.
- 2a) ☒ This action is **FINAL**. 2b) ☐ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

### Disposition of Claims

- 4) ☒ Claim(s) 1,2,4,6,19 and 21 is/are pending in the application.
- 4a) Of the above claim(s) 1,2,4 and 6 is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 19 and 21 is/are rejected.
- 7) ☒ Claim(s) 19 is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_ are subject to restriction and/or election requirement.

### Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☒ The drawing(s) filed on 13 July 2004 is/are: a) ☒ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

### Priority under 35 U.S.C. § 119

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).
- \* See the attached detailed Office action for a list of the certified copies not received.

### Attachment(s)

- 1) ☐ Notice of References Cited (PTO-892)
- 2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
- 3) ☐ Information Disclosure Statement(s) (PTO/SB/08)  
Paper No(s)/Mail Date \_\_\_\_.
- 4) ☐ Interview Summary (PTO-413)  
Paper No(s)/Mail Date. \_\_\_\_.
- 5) ☐ Notice of Informal Patent Application
- 6) ☐ Other: \_\_\_\_.

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## **DETAILED ACTION**

### **Remarks**

Claims 1, 2, 4, 6, and 19, and 21 are pending. Claims 1, 2, 4, and 6 have been withdrawn from consideration. Claims 3, 5, 7-18, and 20 are cancelled. Claim 21 has been newly added.

### ***Claim Objections***

**Claim 19** is objected to because of the following informalities: Claim 19 recites, in relevant part, "...wherein arrangement in a predetermined order of the biomolecule beads and the marker beads in the biomolecule bead array, which corresponds to tube identification information..." does not read properly. Examiner asserts that deletion of the term "which" would lead to Applicant's intended recitation in a more clear manner. Appropriate correction is required.

### ***Claim Rejections - 35 USC § 112***

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

**Claims 19 and 21** are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention. It is unclear if the "tube identification information of a specimen" is a further element of the tube. Applicant has not positively established "tube identification information of a specimen" in the claims. What is the

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tube identification information? Is it a bar code? Examiner asserts that as presently recited, the recitation, "...which corresponds to tube identification information of a specimen..." is a functional limitation, which will be said to be met given prior art that recites the preceding structure to the tube (namely, "the arrangement in a predetermined order of the biomolecule beads and the marker beads in the biomolecule array").

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

(e) the invention was described in (1) an application for patent, published under section 122(b), by another filed in the United States before the invention by the applicant for patent or (2) a patent granted on an application for patent by another filed in the United States before the invention by the applicant for patent, except that an international application filed under the treaty defined in section 351(a) shall have the effects for purposes of this subsection of an application filed in the United States only if the international application designated the United States and was published under Article 21(2) of such treaty in the English language.

**Claims 19 and 21** are rejected under 35 U.S.C. 102(b) as being anticipated by Kambara (6,288,220, corresponding to JP 11-243997).

Kambara discloses a DNA probe array. Kambara discloses a probe array, which comprises an array of a plurality of particles (such as beads) having probes respectively fixed thereon and the probes are capable of binding to different target substances such

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as DNA and proteins (lines 40-45, col. 3). Kambara also discloses that the beads holding the probes are labeled with different dyes or fluorophores, respectively, depending on the kinds of probes held by the beads (lines 58-60, col. 3). Kambara also discloses that the particles are arrayed in a predetermined order (lines 65-67).

Kambara further discloses that the size and shape of the particles holding the probes corresponds to the kind of probes fixed on the surface of the particles, and that also the particles are labeled with different dyes or fluorophores depending on the kind of probes held by the particles (lines 18-34, col. 4). Kambara also discloses that the small spherical particles (beads) having probes are arrayed in a plurality of transparent capillaries and marker particles are placed between the small spherical particles having different species of probes (lines 22-27, col. 17; lines 1-7, col. 18). Kambara further discloses that the marker particles are placed between the small particles having different kinds of probes and the marker particles are labeled with fluorophores different from the fluorophores labeling the small particles (equivalent to the marker particles being optically distinguishable from the beads) (lines 36-40, col. 6). Kambara also discloses a method of detecting a target substance by irradiating the small particles arranged in the tube and detecting the fluorescence emitted (lines 10-22, col. 8+).

Kambara also discloses that the positions of the marker particles on the probe array are reference positions for discriminating the species of the probes on the small particles and inserting a marker between the small particles make it easy to know the arraying order of the probes (lines 40-45, col. 6; lines 5-10, col. 10) (equivalent to arranging the

mark beads and biological beads in a predetermined order, thus corresponding to tube identification information of a specimen).

**Claims 19 and 21** are rejected under 35 U.S.C. 102(e) as being anticipated by Hauser et al. (WO 99/60170), hereafter Hauser.

Hauser discloses spatially-addressable linear arrays of immobilized compounds, such as peptides and polynucleotides (abstract). Hauser discloses a capillary tube having a plurality of non-porous beads aligned in a linear array, each bead having a compound (such as peptides or polynucleotides) immobilized thereon that is identifiable by its spatial address (intrinsically stored identification information) within the linear array (pages 6-9, figs 1&2;claims 1-16, pages 41 and 42). Hauser further discloses that the tube may be composed of virtually any material or mixture of materials that are compatible with the desired conditions of use. Hauser discloses that the tube is preferably transparent to the wavelength of light used to illuminate and detect fluorophore labels commonly used in biological assays; such a preferable material would be glass (pages 12 and 13).

### ***Response to Arguments***

Applicant's arguments filed November 9<sup>th</sup>, 2007 have been fully considered but they are not persuasive.

**With regards to claims 19 and 21**, Applicant argues that Kambara (6,288,220, corresponding to JP 11-243997) does not disclose, teach, or suggest that the "arrangement in a predetermined order of the biomolecule beads and the marker beads

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in the biomolecule bead array, corresponds to tube identification information of a specimen... Examiner asserts that as presently recited, the recitation, "...which corresponds to tube identification information of a specimen..." is a functional limitation, which will be said to be met given prior art that recites the preceding structure to the tube (namely, "the arrangement in a predetermined order of the biomolecule beads and the marker beads in the biomolecule array"). As Kambara meets the structural limitations that precede the functional limitation of "corresponds to tube identification information of a specimen", the functional limitation is met.

**With regards to claims 19 and 21**, Applicant argues that Hauser (WO 99/60170) does not disclose, teach, or suggest that the "arrangement in a predetermined order of the biomolecule beads and the marker beads in the biomolecule bead array, corresponds to tube identification information of a specimen..." Examiner asserts that as presently recited, the recitation, "...which corresponds to tube identification information of a specimen..." is a functional limitation, which will be said to be met given prior art that recites the preceding structure to the tube (namely, "the arrangement in a predetermined order of the biomolecule beads and the marker beads in the biomolecule array"). As Hauser meets the structural limitations that precede the functional limitation of "corresponds to tube identification information of a specimen", the functional limitation is met.

***Conclusion***

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Neil Turk whose telephone number is 571-272-8914. The examiner can normally be reached on M-F.


If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Jill Warden can be reached on 571-272-1267. The fax phone number for the organization where this application or proceeding is assigned is 571-273-8300.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free). If you would like assistance from a USPTO Customer Service Representative or access to the automated information system, call 800-786-9199 (IN USA OR CANADA) or 571-272-1000.

NT

  
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